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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,890	01/07/2002	Craig E. Smith	016026-9148	5555

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EXAMINER

CALAMITA, HEATHER

ART UNIT PAPER NUMBER

1637

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/041,890	<b>Applicant(s)</b> SMITH ET AL.	
	<b>Examiner</b> Heather G. Calamita, Ph.D.	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 22-60 is/are pending in the application.  
4a) Of the above claim(s) 29-56 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-6, 22-28 and 57-60 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. Amendments of February 22, 2005 have been received and entered in full. Claims 1-6, 22-60 are pending. Claims 1-6, 22-28 and new claims 57-60 are under examination. Any objections and rejections not reiterated below are hereby withdrawn.

### *Claims interpretation*

2. The instant specification defines the silica magnetic particles as “a magnetic particle comprised of silica in the form of silica gel, siliceous oxide, solid silica such as glass or diatomaceous earth, or a mixture of two or more of the above. The term "silica gel" as used herein refers to chromatography grade silica gel, a substance which is commercially available from a number of different sources. The specification, however, does not disclose any structure different from that which is disclosed in Josephson (USPN 4,672,040, 06/09/1987). The MPEP states “Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established.” In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Josephson is silent as to the amount of target material per milligram of particles, however as the products are structurally identical the amount of target material per milligram of particles remains anticipated by Josephson.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Josephson (USPN 4,672,040 06/09/1987).

Josephson teaches a method for isolating biological target material from other material in a medium by contacting the medium with the biological target with silica magnetic particles that reversibly bind the target to create a complex of the magnetic particle and the target material (see whole document, especially col. 18 lines 44-68, col. 7 lines 66-67, col. 8 lines 1-9). He teaches removing the complex from the medium with a magnet, and separating the target material from the complex by eluting and obtaining the target material (see col. 30 lines 55-60). Additionally, he teaches nucleic acids as isolated materials (see col. 16 lines 18). He also teaches using siliceous oxide coated magnetic particles (see col. 7 lines 66-67, col. 8 lines 1-5).

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6 and 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Josephson (USPN 4,672,040 06/09/1987) in view of Gautsch et al. (USPN 6,613,895 B1 09/02/2003).

The teachings of Josephson are described previously.

Josephson does not teach 60% of the biological target eluted from the particles. He also does not teach using a chaotropic salt, incubating the mixture of magnetic particles with the target at room temperature or a washing step with a wash buffer.

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Gautsch et al. teach at least 60% of target material, specifically nucleic acids, eluted from the complex of silica particles and target material. Gautsch et al do not teach that any contaminants are present in the elute (see col. 14 lines 30-40). Furthermore they teach a method of isolating plasmid DNA from other materials in a medium using silica particles and a chaotropic salt to help the DNA adhere to the silica particles (see col. 13 line 24, col. 8 lines 48-54). They also teach the chaotropic salt as guanidine thiocyanate (see col. 5 lines 6-12). They teach a salt concentration of between 0.1 M and 7 M (see col. 5 lines 62-63). Additionally they teach washing the silica particles after removing them from the medium before eluting the bound DNA (see col. 8 lines 61-66). They teach the wash buffer as a mixture of alcohol and salt, at least 30% by volume (see col. 11 lines 28-30).

One of ordinary skill in the art at the time the invention was made one would have been motivated to apply Josephson's silica coated magnetic particles to Gautsch's method of isolating nucleic acid with silica particles to achieve more rapid and simplified separations of target analytes. Josephson states magnetic particles are selectively recovered, promote homogenous reaction conditions and facilitate separation of bound from unbound analytes (see col. 2 lines 66-67 and col. 3 lines 1-2). It would have been prima facie obvious to apply Josephson's magnetic silica particles to Gautsch's method of isolating nucleic acids in order to achieve the expected advantage of a cleaner method isolating nucleic acids that is less time consuming and yields a cleaner product.

5. Claims 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Josephson (USPN 4,672,040 06/09/1987) in view of Gautsch et al. (USPN 6,613,895 B1 09/02/2003) and in further view of Uematsu et al. (USPN 5,945,525, 08/31/1999).

The teachings and suggestions of Josephson and Gautsch et al. are described previously.

The combination of Josephson and Gautsch et al. does not teach or suggest a total pore volume of at least 0.2 ml/g of particle mass.

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Uematsu et al. teach silica beads with a diameter of between 3-10 microns with a total pore volume of at least 0.2 ml/g of particle mass (see col. 3 lines 62 and lines 64-64). Uematsu et al. are silent as to the method used to determine the pore volume, however as the products are structurally identical, the method of assessing the pore volume is irrelevant.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the pore volume of the bead as taught by Uematsu et al. (USPN 5,945,525, 08/31/1999) with the method as taught by Gautsch et al. (USPN 6,613,895 B1 09/02/2003) since Uematsu et al. state, "the magnetic silica particle has an average surface pore diameter of about 0.1 to about 60 nm and has a pore volume of about 0.01 to about 1.5 ml/g (see col. 3 lines 59-62). An ordinary practitioner would have been motivated to use the pore volume of the bead as taught by Uematsu et al. (USPN 5,945,525, 08/31/1999) with the method as taught by Gautsch et al. (USPN 6,613,895 B1 09/02/2003) in order to maximize the amount of nucleic acid that binds the surface of the magnetic bead.

#### *Response to Arguments*

6. Applicants' arguments filed February 22, 2005, have been fully considered but they are not persuasive.

With respect to the 102 (a) rejections of claims 1-4 applicant argues the instantly claimed particles are not identical to the particles of Josephson, as Josephson does not disclose or suggest particles that are capable of reversibly binding adsorbents or target material (ie nucleic acids).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., direct complex between the particle and the target material) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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Applicant assumes direct binding of the particle to the target material, however, the claim does not require a direct complex. The claim is sufficiently broad as to allow for either a direct complex between the particle and the target material or an indirect complex between the target material and the particle.

At column 19 Josephson shows isolation of DNA fragments by binding to nucleic acids immobilized on the particle. The magnetic particle has covalently attached nucleic acids to which other complementary nucleic acids are hybridized. It is this second complementary nucleic acid which binds reversibly. The bond between the hybridized nucleic acids is reversible as the hybridization can be denatured with heat or chemical treatment. Therefore, the particle of Josephson meet the limitation recited in the instant claims.

7. Applicant's arguments, filed September 17, 2004, with respect to the rejection(s) of claim(s) 5, 6 and 22-28 under 103(a) have been fully considered but they are not persuasive. Applicant's primary argument with the 103 rejection is Gautsch et al. (USPN 6,613,895 B1 09/02/2003) teaches *an amount sufficient to bind at least two to three micrograms of nucleic acid* and that Gautsch et al. refers to a mass of particles sufficient to recover a minimum mass of nucleic acids. Applicant's arguments with respect to the teachings of Gautsch et al. are moot in view of clarification of the application of Josephson's teachings.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### *Correspondence*

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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JEFFREY FREDMAN  
PRIMARY EXAMINER

4/14/05